DETAILED ACTION

The amendment filed 8/8/09 is acknowledged. Claims 3-4, 5-8, 15 and 18 are being presented for examination.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-8, 15 and 18 rejected on the ground of nonstatutory double patenting as being unpatentable over claims 1-4 of U. S. Patent No.7, 465,576 Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same subject matter of treating infections by using the same materials and the same process steps...

Therefore, the claims are co-extensive.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 3-6 are rejected under 35 U.S.C. 101 because the claims read on the organism per se which is found in nature and thus, is unpatentable to applicant. Consequently, the claims do not embody patentable subject matter as defined in 35 USC 101. See, e.g., American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974); American Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931); Funk Brothers Seed. Co. v. Kalo Innoculant Co.., 33 U.S. 127 (1948); Diamond v. Chakrabarty, 206 U.S.P.Q. 193 (1980).

It is suggested that applicant use the language "a biologically pure culture" in connection with the strain to identify a product that is not found in nature and to indicate the hand of man.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments do not address the product of nature rejection. They are not pertinent to the rejection made.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 6-8, 15 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 6-8, 15 and 18 are confusing in that the amount of the strain *Lactobacillus casei* FERM BP-10059 in the various compositions and methods is not set forth in the claims with any particularity. The concentrations intended for the strain and the antibiotic or disinfectant(s) cannot be readily assessed in the context of the claimed invention. Similarly, there is no clear indication whether the compositions contain live or dead bacteria.

The nature of the "preservative" in claim 4 is unclear, since there is no indication as to what is intended to be "preserved" with an unknown "preservative" in a composition containing unknown amounts of a microorganism. Is it a food composition?

Claims 7 and 15 are vague and indefinite in that the preamble is directed to a "method for treating infections in humans and animals", while the respective steps appear to be directed to a specific infection, i.e., periodontal disease.

Claim 6 is confusing and vague in that the nature of the "preventative or therapeutic agent" cannot be readily determined, since it requires an antibiotic effective in humans, animals and plants in unknown amounts. In addition, it is unclear what is intended to be prevented.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-4, 5-8, 15 and 18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a specific strain of *L. casei*. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It appears that a deposit was made in this application as filed as noted on page 8, paragraph 4 of the specification. However, it is not clear if the deposit meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner.

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.

6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.

7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

The deposit requirement is not fulfilled, because a statement is missing averring that that **all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.**

Therefore the rejection is deemed proper and it is adhered to.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matrozza U.S. Patent No. 4,579,740

The claim is directed to a composition comprising unknown amounts of a bacterial strain of *L. casei* and of a preservative.

Matrozza teaches a composition comprising a bacterial strain of *L. casei* and a preservative which reads on the claimed composition. See e,g., claim 1. Even though the strains are not necessarily the same, the amount as claim designated does not patentably distinguish the invention.

Claim 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hata *et al.* (U.S. Patent No. 4,314,995)

The claims are directed to a composition comprising unknown amounts of a bacterial strain of *L. casei* and of a preservative or of an antibiotic.

Hata *et al.* teach a composition comprising a bacterial strain of *L. casei* and an antibiotic, which reads on the claimed composition. See, e.g., Table 1 and Table 7.

Even though the strains are not necessarily the same, the composition as claimed does not patentably distinguish the invention. An antibiotic is deemed to act as a preservative at least to some extent.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Asahara *et al.* (Antimicrobial Agents and Chemotherapy, June 2001, Vol. 45, p. 1751–1760) taken with Ouwehand *et al.* (Journal of Food Science, Vol. 66, No. 6, pages 856-858, 2001.)

The claims are directed to a composition comprising unknown amounts of a bacterial strain of *L. casei* and a preservative or an antibiotic.

The cited references teach a composition comprising a bacterial strain of *L. casei* and an antibiotic, which reads on the claimed composition. See, e.g., See, e.g., Asahara *et al.* page 1753, paragraph 2, et seq. and Ouwehand *et al.*, page 856, last 2 lines.

Even though the strains are not necessarily the same, the composition as claimed does not patentably distinguish the invention. An antibiotic is deemed to act as a preservative at least to some extent.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651